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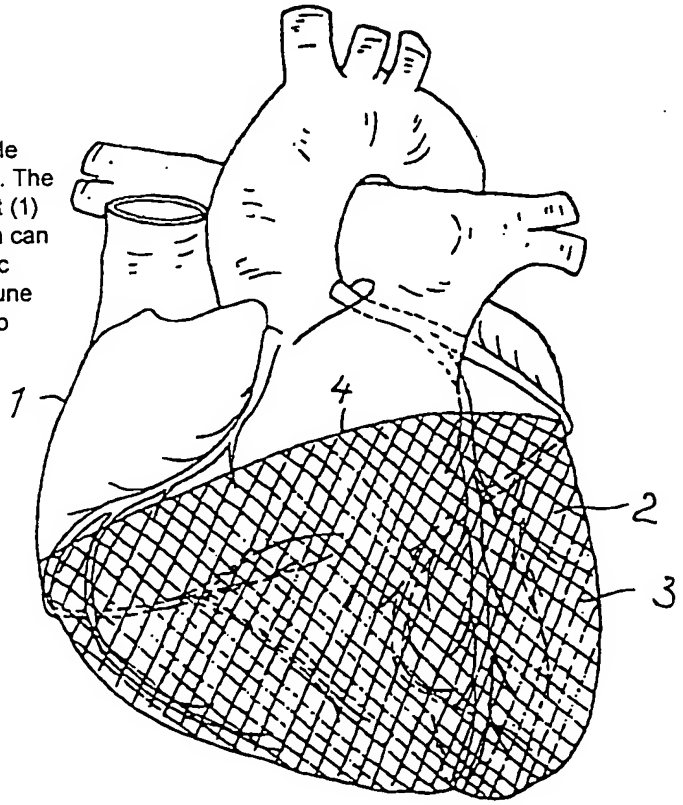
(54) Title: BAG FOR AT LEAST PARTIALLY ENVELOPING A HEART*

(57) Abstract

The invention relates to a bag (2) with flexible walls for at least partially enveloping a heart (1). The bag is meant to surround at least part of a heart (1) and counteract distension of the heart (1) which can be caused by inflammatory illness of the cardiac muscle, e.g. a virus infection, or in an autoimmune process. Use of this bag (2) makes it possible to avoid heart transplants in many cases.*



*Translator's note: The English title and abstract have been taken from the published application; some expressions are translated differently in the following translation made of the complete specification.

Pouch for at least partially enveloping a heart

The invention relates to a pouch for at least partially enveloping a heart.

Inflammatory diseases of the heart muscle caused both by viral infections and also by autoimmune processes can result in the volume of the heart becoming larger. When that occurs beyond a critical measure, there ensues progressive dilatation of the heart, which can be explained by Laplace's law. As the volume of the hollow body formed by the left ventricle becomes larger, the tensions in the wall of that hollow body also increase. That leads to overstressing of the muscle fibrils and to a departure from their ideal range of expansion. At that stage of overexpansion there generally remains a residual volume in the heart. The muscle fibrils then have to work against an initially higher wall tension, which leads to their further expansion. That results in a vicious circle which leads to increasing overexpansion of the heart with consequent heart failure.

Even though it is, in principle, possible to treat that development in the early stages with drugs by reducing the preload using ACE inhibitors, that is not always successful. Furthermore, because clinical manifestations are minor at first, the condition is often not noticed until a critical measure has already been exceeded. Heart transplantation is then frequently the only possible treatment available.

DE 295 17 393 U1 discloses a pouch of the type mentioned in the preamble of claim 1, which is not expansible and which is intended for averting dilatation of the myocardium caused by end diastolic pressure. Although that known pouch does prevent overexpansion of the wall of the heart, that action is deployed suddenly when the volume of the heart reaches the volume enclosed by the pouch. That sudden action has a disadvantageous effect on the heart. Furthermore, folds may be formed in the pouch when the volume of the heart is smaller than the volume defined by the size of the pouch.

The problem underlying the invention is to provide a pouch for at least partially enveloping a heart, which pouch counteracts overexpansion of the heart without impairing its function.

The problem underlying the invention is solved by the teaching given in the characterising clause of claim 1.

The fundamental idea of the invention consists in partially taking up the tensions in the wall of the hollow body formed especially by the left ventricle and thereby relieving the muscle fibrils. That general action alone can already result in preventing the volume of the heart enlarging beyond a critical measure. The pouch according to the invention consequently has a supportive action.

The pliancy of the pouch according to the invention can be accomplished in various ways. A most simple form consists in the pouch always exerting the same force, substantially irrespective of its expansion, on the heart, so that the heart is always relieved of substantially the same tension irrespective of its volume. Another advantageous practical form of the invention consists in the wall of the pouch being elastic so that the tension it exerts and, consequently the relief of the heart, becomes greater as the volume increases. It is also possible for the expansion characteristics to take a different course depending on the relief desired. For example, it is advantageous for the elasticity of the wall of the pouch to decrease as the expansion increases in order to take account of the specific tension in the wall of the heart. It is also advantageous for the expansion to have a limit value such that further enlargement of the heart cannot occur once that limit value has been reached. Because of the pliancy of the pouch according to the invention in contrast to the known pouch, that limit value is reached not suddenly but gradually, so that there is no possibility of the pouch acting in a jolting manner. The limit value of the pouch should advantageously be a volume of the pouch that corresponds to the volume of the heart at the stage of maximum diastolic filling. Viewed overall, the nature of the pliancy and the course of the expansion curve of the pouch can be used to determine and modify the relief of the muscle fibrils effected by the pouch.

For fitting the pouch according to the invention, the pericardium can be opened by thoracoscopic means and the pouch according to the invention can then be drawn over the heart muscle. That is advantageously carried out approximately as far as the *anulus fibrosus*, that is to say the valve plane, where the pouch is fixed.

According to a development of the invention, the volume of the pouch in the unexpanded state is smaller than the volume of the heart at the stage of minimum filling, thereby ensuring that the pouch is in contact with the heart in all stages of expansion.

In a practical form of the invention wherein the wall of the pouch is elastic and the expansion has a limit value, it is advantageous for the pouch to comprise elastic and inelastic material. The elastic material therein may determine the course of expansion while the inelastic material may determine the limit value for the expansion. For the practical implementation thereof it is advantageous for the elastic material to consist of sheet material or a weave or knit made from threads, into which sheet material or weave or knit there are incorporated threads made from substantially inelastic material. The threads made from substantially inelastic material are advantageously incorporated in the sheet material or weave or knit so as to be capable of longitudinal movement.

In that practical form it is especially advantageous for the threads made from substantially inelastic material to extend out from the pouch in places and consequently for their length to be adjustable by being knotted in places and for the volume and/or shape of the pouch to be matched to the volume and/or shape of the pouch* on maximum diastolic filling. In that arrangement, the threads made from substantially inelastic material advantageously run from the edge of the opening of the pouch to a tip thereof located essentially opposite. The threads can then extend out from the pouch in the region of its tip.

In the practical form wherein the elastic expansion of the pouch has a limit value, it is advantageous for the pouch to consist of a weave or knit made from threads that are not expansible but that are flexible and are formed so as to be rippled, especially wave-shaped and/or zigzag-shaped, transversely to their longitudinal dimension. The way in which they are formed allows the course of expansion and the limit value to be determined.

The wall of the pouch advantageously consists of preferably thermoplastic material, which allows the shape of the pouch to be simply formed and matched to the shape of the heart, or of biological material, for which denatured bovine pericardium is especially suitable.

In order to achieve permeability to gas, especially oxygen, and to liquid, the wall of the pouch according to the invention is advantageously constructed as a net, which

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Translator's note: Claim 10 reads 'heart' instead of 'pouch' at this point.

may advantageously consist of open-cell foamed material, for example silicone foamed material. Such a foamed material is capable of ensuring that the pressure is applied very evenly and gently to the heart muscle. Furthermore, such a foamed material has the ability to absorb a gliding agent, for example serous liquid, so that the pouch is able to glide easily against the pericardium. The gliding agent is advantageously a biological gliding agent, for which purpose a hyaluronic acid manufactured by means of genetic engineering is especially suitable. By incorporating a gliding agent in the foamed material beforehand, the ability to glide easily is ensured from the start, thereby averting initial, self-reinforcing irritation of the pericardium.

When the wall of the pouch consists according to the invention of a net, that net can advantageously be formed by a sheet material provided with openings. Such sheet material is capable of transferring the pressure of the pouch onto the heart over a large area.

The net forming the wall of the pouch according to the invention may consist of a weave or knit. By that means the expansion behaviour of the pouch can be matched within wide limits to actual conditions.

Wholly irrespective of whether the net forming the wall of the pouch consists of sheet material, a knit or a weave, it is always advantageous to provide, in addition, a coating comprising open-cell foamed material, which ensures that the forces are transferred evenly and which is, in addition, capable of absorbing a gliding agent.

When the elasticity of the wall of the pouch decreases as the expansion increases or when the expansion has a limit value, an especially advantageous practical form of the invention lies in the pouch consisting of two kinds of threads or fibres made from plastic material, of which the one kind has a higher, preferably substantially higher, forming temperature than the other kind, with the one kind being elastic and the other kind being, in contrast, less, preferably substantially less, elastic. When disparate fibres of those kinds are used it is possible to achieve the shape of the pouch by means of thermoplastic forming at a temperature at which the less elastic, or inelastic, material, but not the more elastic material, is enduringly formed at a pre-specified forming temperature. The less elastic, or inelastic, material therefore determines the maximum expansion of the pouch while the elastic, and not enduringly formed, material exerts constricting forces on the heart below the maximum shape determined by the less elastic, or inelastic, material.

According to a development of the invention, the plastic material used for manufacture of the pouch is thermoplastic. That has the advantage not only that the pouch can be simply placed in a prefabricated mould but also that it is possible to mould the pouch, or to modify its shape, before or during the operation in order to match it to the dimensions found for that portion of the heart which is to be surrounded.

According to a development of the invention the foamed material consists of silicone.

The problem underlying the invention is also to provide a method for the manufacture of a pouch according to claim 1. The solution to that problem consists in manufacturing a mould in the shape of that portion of the heart which is to be surrounded and drawing a gas- and/or liquid-permeable sheet material or a net or knit made from thermoplastic material over the mould while heat is applied.

The shape of the mould is advantageously produced or determined by imaging the shape of the heart to be surrounded and producing the mould with reference to that image. The imaging may be performed in any desired manner, for example X-ray imaging or computerised tomography.

The invention will be illustrated in greater detail with reference to the drawing, in which

Fig. 1 shows a first embodiment of the invention,

Fig. 2 shows a second embodiment of the invention and

Fig. 3 shows a third embodiment of the invention.

The drawing shows, in diagrammatic form, a heart 1, which is partially enveloped by a pouch 2, the wall of which consists of a net 3. The pouch 2 extends into the region of the *anulus fibrosus*, that is to say the valve plane, and is there fixed, along a terminating edge 4, to the heart muscle, which fixing is not shown in the drawing. The net 3 consists of elastically pliant threads. The volume of the pouch 2 in the non-expanded state is less than the volume of the heart 1 at the stage of minimum filling, thereby ensuring that the net is in contact with the wall of the heart 1 in all stages of expansion.

Fig. 2 shows a second practical form of the invention, which constitutes a modification of the practical form according to Fig. 1. The same or corresponding parts are provided with the same reference numerals. The difference lies in the fact that, from the terminating edge 4, threads 5 converge on a central point 6, while threads 7

run in an essentially circumferential direction. At crossing points 8, the threads 5 and 7 are joined to one another, either by means of fusion, adhesion or by means of immersion of the whole pouch 2 in a mass, for example foamed material, and subsequent solidification thereof.

Fig. 3 shows an embodiment of a pouch 9, which consists of a knit of threads 10, which run from a terminating edge 11 to a central point 12, where the thread ends 13 are extended, which ends 13 can, after the pouch 9 has been fitted, be drawn tight in desired manner and knotted together in order to match the pouch 9 to the shape and volume of the heart 1.

Patent claims

1. Pouch (2) for at least partially enveloping a heart (1), **characterised in that** the wall of the pouch (2) is pliant*.

2. Pouch according to claim 1, **characterised in that** the wall of the pouch (2) is elastic.

3. Pouch according to claim 2, **characterised in that** the elasticity of the wall of the pouch (2) decreases as expansion increases.

4. Pouch according to claim 3, **characterised in that** the expansion has a limit value.

5. Pouch according to claim 4, **characterised in that** the limit value lies at a volume of the pouch that corresponds to the volume of the heart at the stage of maximum diastolic filling.

6. Pouch according to claim 1, **characterised in that** the volume of the pouch in the expanded state corresponds maximally to the volume of the heart at the stage of minimum systolic filling.

7. Pouch according to claim 4, **characterised in that** the pouch comprises elastic and inelastic material.

8. Pouch according to claim 7, **characterised in that** the elastic material consists of sheet material or a weave or knit made from threads, into which sheet material or weave or knit there are incorporated threads made from substantially inelastic material.

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*Translator's note: The published abstract translates the German adjective 'nachgiebig' as 'flexible'; however, I understand the German to mean capable of deformation and/or of stretching, but not necessarily of returning to its original state after stretching. The definitions of 'nachgeben' (the verb from which the adjective derives) given, for example, in Wahrig's German Dictionary include the German for 'to bend, to expand, to yield, to give way'.

9. Pouch according to claim 8, **characterised in that** the threads made from substantially inelastic material are incorporated in the sheet material or weave or knit so as to be capable of longitudinal movement.

10. Pouch according to claim 9, **characterised in that** the threads made from substantially inelastic material extend out from the pouch in places and consequently their length is adjustable by being knotted in places and the volume and/or shape of the pouch can be matched to the volume and/or shape of the heart on maximum diastolic filling.

11. Pouch according to claim 10, **characterised in that** the threads made from substantially inelastic material run from the edge of the opening of the pouch to a tip thereof located essentially opposite.

12. Pouch according to claim 11, **characterised in that** the threads extend out from the pouch in the region of its tip.

13. Pouch according to claim 4, **characterised in that** the pouch consists of a sheet material, a weave or knit, which has folding, rippling, pleating or the like.

14. Pouch according to claim 4, **characterised in that** the pouch consists of a weave or knit made from threads that are not expansible but that are flexible and are formed so as to be rippled, especially wave-shaped and/or zigzag-shaped, transversely to their longitudinal dimension.

15. Pouch according to claim 14, **characterised in that** the rippling is thermally fixed.

16. Pouch according to claim 4, **characterised in that** the pouch consists of a knit and the threads of the knit are not-expansible but are flexible.

17. Pouch according to claim 1, **characterised in that** the wall of the pouch (2) consists of plastic material or biological material.

18. Pouch according to claim 17, **characterised in that** the biological material is denatured bovine pericardium.

19. Pouch according to claim 1, **characterised in that** the wall is constructed as a net (3).

20. Pouch according to claim 19, **characterised in that** the net (3) consists of open-cell foamed material.

21. Pouch according to claim 19, **characterised in that** the net (3) consists of a sheet material provided with openings.

22. Pouch according to claim 19, **characterised in that** the net (3) consists of a weave or knit.

23. Pouch according to claim 21 or claim 22, **characterised in that** the sheet material or weave or knit is coated with open-cell foamed material.

24. Pouch according to claim 3 or claim 4, **characterised in that** the pouch (2) consists of two kinds of threads or fibres made from thermoplastic material, of which the one kind has a higher, preferably substantially higher, forming temperature than the other kind, with the one kind being elastic and the other kind being, in contrast, less, preferably substantially less, elastic.

25. Pouch according to claim 24, **characterised in that** the plastic material is thermo-plastic.

26. Pouch according to claim 20 or claim 23, **characterised in that** the foamed material consists of silicone.

27. Pouch according to claim 20 or claim 23, **characterised in that** the foamed material comprises a gliding agent.

28. Pouch according to claim 20, **characterised in that** the gliding agent is a biological gliding agent.

29. Pouch according to claim 21, **characterised in that** the gliding agent is manufactured by means of genetic engineering.

30. Pouch according to claim 29, **characterised in that** the gliding agent manufactured by means of genetic engineering is hyaluronic acid.

31. Method of manufacturing a pouch according to claim 1, **characterised in that** a mould is manufactured in the shape of that portion of the heart which is to be surrounded and a gas- and/or liquid-permeable sheet material or a net or knit made from thermoplastic material is drawn over the mould and moulded while heat is applied.

32. Method according to claim 31, **characterised in that** the shape of the heart to be surrounded is imaged and the mould is produced with reference to that image.

33. Pouch according to claim 1, **characterised in that** the wall of the pouch consists of polytetrafluoroethylene, especially of open-cell foam made from polytetrafluoro-ethylene.

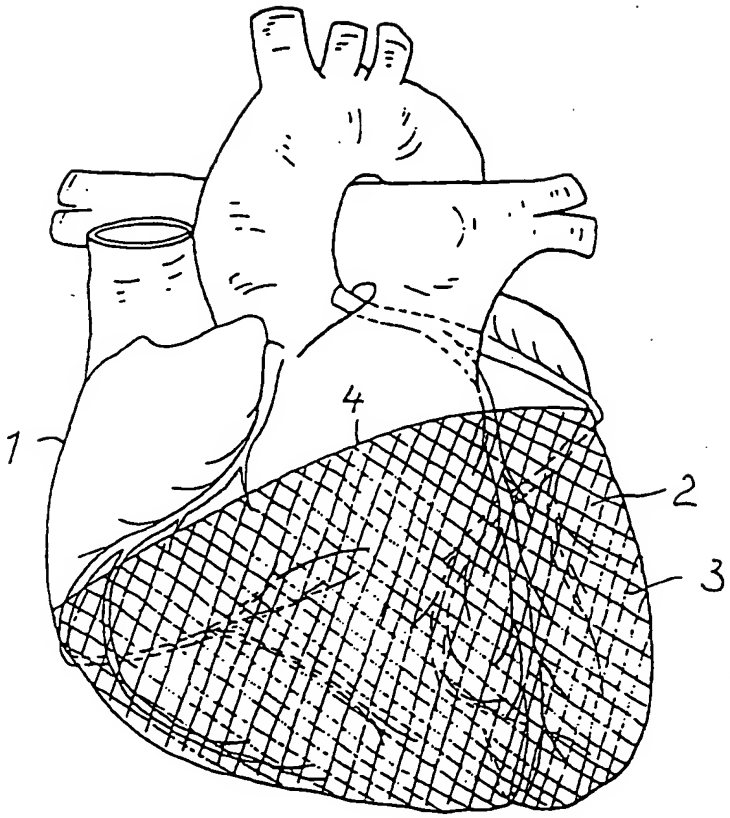

FIG. 1

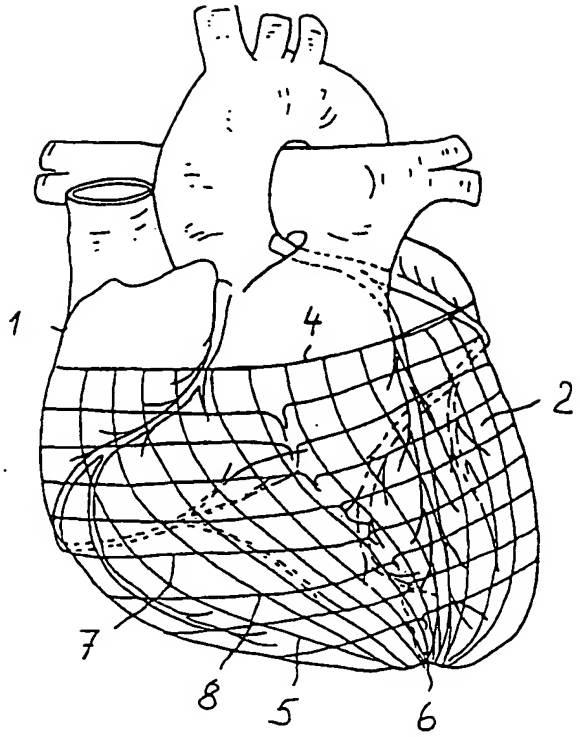

FIG. 2

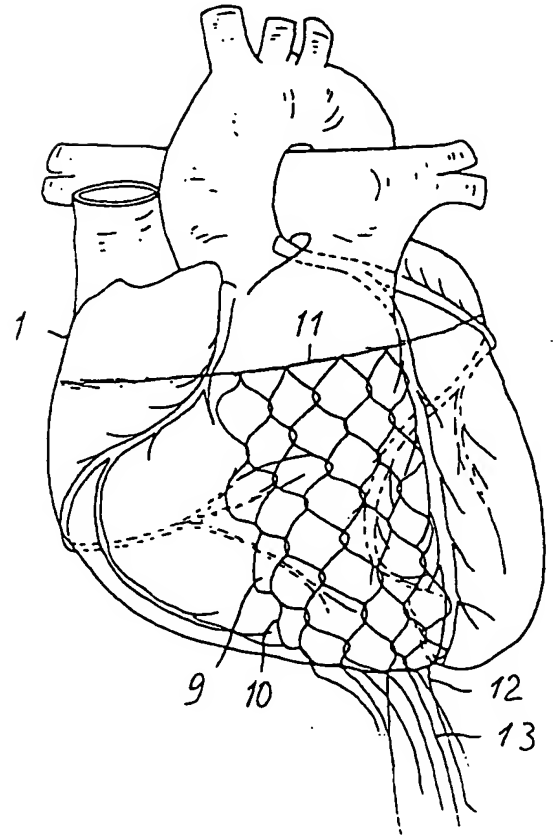

FIG. 3

INTERNATIONAL SEARCH REPORT

Int. onal Application No
PCT/EP 98/03619

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/00

According to International Patent Classification(IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 983 863 A (JANKE WALTER H ET AL) 5 October 1976 see the whole document ---	1,2,17, 19,22
X	FR 2 737 106 A (COUSIN BIOTECH) 31 January 1997 see the whole document ---	1,2,17, 19,21,22
X	US 4 690 134 A (SNYDERS ROBERT V) 1 September 1987 see column 3, line 4 - column 4, line 17; figures ---	1,2,17
P,X	US 5 702 343 A (ALFERNESS CLIFTON A) 30 December 1997 see the whole document	1-12,17, 19,22,24
A	 --- -/--	31

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
20 October 1998	27/10/1998

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Int· ional Application No
PCT/EP 98/03619

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 16601 A (GORE & ASS) 6 June 1996 see page 10, line 20 - page 13, line 2; figures -----	1,17,25, 31-33

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INTERNATIONAL SEARCH REPORT

..ıformation on patent family members

Inte: ınal Application No
PCT/EP 98/03619

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FR 2737106 A	31-01-1997	NONE	
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WO 9616601 A	06-06-1996	AU 1608895 A	19-06-1996